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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/955,644 | 09/18/2001 | Eric Silverberg | 1893 | 1184 |

7590 08/23/2006

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| EXAMINER |
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GHALI, ISIS A D

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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,644

Applicant(s)

SILVERBERG ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 06/13/2006.

Claims 1-20 are pending and included in the prosecution.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-6, 8-17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/08229 ('229).

WO '229 disclosed pressure sensitive adhesive composition comprising acrylic polymer comprising 40-95% of one or more A monomers selected from the group consisting of alkyl acrylates and/or alkyl methacrylates, and up to 60% of one or more B monomers (page 2, lines 5-23). Preferred A monomers include 2-ethylhexyl acrylate, n-

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butyl acrylate, and methyl methacrylate (page 4, lines 3-14). B monomers include substituted acrylamide, methacrylonitrile, and vinyl acetate (page 4, lines 25-27; page 5, lines 7-12). The polymer composition is used to form matrices for transdermal drug delivery device (page 2, lines 5-13; page 3, lines 29-30). The transdermal device comprises a backing layer, a matrix layer comprising the polymer composition and a therapeutic active agent, and a release liner (page 2, line 6; page 13, line 22; page 14, lines 16-17, 26). WO '229 further contemplates various drugs for delivery by the device including analgesics such as fentanyl (page 12, line 28). The pressure sensitive adhesive has a glass transition temperature of -10^0 C (page 11, lines 4-5). The reference does not teach any cross-linking agent in the polymer composition or any functional groups containing reactive hydrogen.

Response to Arguments

3. Applicant's arguments filed 06/13/2006 have been fully considered but they are not persuasive. Applicants traverse the anticipatory rejection of claims 1-6 and 8-17 over WO 229 by arguing that the reference does not anticipated the claims because the copolymer disclosed by the reference comprises one or more A monomer, one or more optional B polymer, and macromonomer, and the macromonomer is required and necessary component of the copolymer, while the present polymer comprising monomer selected from the group consisting of alkyl acrylate monomers and alkyl methacrylate monomers only, and polymerizable non-cyclic nitrogen-containing monomer.

In response to this argument, it is argued that the A monomer and the macromonomer disclosed by WO '299 both read on the alkyl acrylate and/or alkyl methacrylate instantly claimed, and B polymer reads on the non-cyclic nitrogen containing polymer. Applicants' polymer as claimed can contain both alkyl acrylate and/or alkyl methacrylate, and WO '229 disclosed monomer A is alkyl acrylate and the macromonomer is alkyl methacrylate. Applicants are not disclosing any length of the monomer, thus the macromonomer disclosed by WO '229 meet the limitation of monomer disclosed by applicant. The preparations disclosed by WO '229 all contain the optional B monomer such as vinyl acetate and dimethylacrylamide. On page 18, lines 1-5, WO '229 disclosed copolymer preparation of alkyl acrylate: dimethylacrylamide: polymethacrylate at a ratio of 50:40:10, i.e. total amount of alkyl acrylate and alkyl methacrylate together is 60% and the amount of non-cyclic nitrogen containing monomer is 40%. On page 18, lines 14-17, WO '229 disclosed same preparation of alkyl acrylate: dimethylacrylamide: polymethacrylate but at a ratio 63:27:10, i.e. total amount of alkyl acrylate and alkyl methacrylate together is 73% and the amount of non-cyclic nitrogen containing monomer is 27%. The preparation on page 22 of WO '229, lines 15-18 is alkyl acrylate: vinyl acetate: polymethacrylate at a ratio of 58:37:5, i.e. total amount of alkyl acrylate and alkyl methacrylate together is 63% and the amount of non-cyclic nitrogen containing monomer is 37%. On page 23, lines 14-17, WO '229 disclosed same preparation of alkyl acrylate: vinyl acetate: polymethacrylate at a ratio of 53:37:10, i.e. total amount of alkyl acrylate and alkyl methacrylate together is 63% and the amount of non-cyclic nitrogen containing monomer is 37%. Therefore, WO '229

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disclosed the claimed polymer formed of the same monomers at ranges within the claimed ranges. WO '229 meets the limitation of claims 1-6 and 8-17.

4. Claims 1-11, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,077,527 ('527).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '527 disclosed a pressure sensitive adhesive composition for use in transdermal drug delivery devices comprising at least 40% by weight of alkyl acrylate including n-butyl and 2-ethylhexyl acrylate, and 10-60% by weight of substituted acrylamide or methacrylamide including t-octyl acrylamide (abstract; col.2, lines 45-60; col.3, lines 60-67; col.4, lines 8-16). The Tg of the composition is calculated by the examiner to be below 10⁰C. The reference does not disclose any reactive groups after the cross-linking.

Response to Arguments

5. Applicant's arguments filed 06/13/2006 have been fully considered but they are not persuasive. Applicants traverse the anticipatory rejection of claims 1-11 and 14 over

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US '527 (Tan's reference) by arguing that US '527 is disqualified as prior art because the subject of US '527 and the subject matter instantly claimed were, at the time the claimed invention was made, owned by the same individual (National Starch and Chemical Investment Holding Incorporation).

In response to this applicants' argument, it is argued that according to the statute under U.S.C. 102 (e), US '527 is qualified and constitutes prior art based on earlier effective filing date, October 28, 1997. Applicants failed to overcome the reference by showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131, as required by the U.S.C. 102 (e) statute. The Rule 1.131 declaration filed 02/23/2006 showed that the present invention was prepared and executed prior to June 20, 2000 which is the publication date of the US '527, and did not show that the present invention was prepared and executed before October 28, 1997, which the effective filing date of US '527. Therefore, US '527 is qualified under 102 (e).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicants' have overcome the rejection of claims 7 and 18-20 under U.S.C.103 (a) over US '527 by establishing common ownership according to MPEP § 706.02(I)(1) and § 706.02(I)(2) by a statement concerning that the subject matter of US '527 and the subject matter instantly claimed were, at the time the claimed invention was made, owned by the same individual (National Starch and Chemical Investment Holding Incorporation).

Accordingly, claims 7 and 18-20 will remain obvious under 35 U.S.C. 103(a) over WO '229 alone as discussed in the previous office action.

8. Claims 7 and 18-20 are rejected under 35 U.S.C. 103(a) as being obvious over WO 96/08229 ('229).

The teachings of WO '229 are discussed above.

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However, WO '229 does not teach the specific t-octyl acrylamide claimed in claims 7 and 19, or the combination of 2-ethylhexyl acrylate and methyl acrylate as claimed in claim 18.

The art recognized the suitability of N-substituted methacrylamide monomer in pressure sensitive adhesive used in transdermal devices, therefore, the specific species t-octyl acrylamide does not impart patentability to the claims, absent evidence to the contrary. Applicants failed to show superior and unexpected results obtained from the combination of specific species.

Response to Arguments

9. Applicant's arguments filed 06/13/2006 have been fully considered but they are not persuasive.

Applicants hereby repeat the argument regarding WO '229, and in response the examiner's response on section 3 is repeated.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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Isis Ghali